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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,061	03/10/2004	Lawrence J. Wangh	21578-010CON	5694

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EXAMINER

CROUCH, DEBORAH

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/798,061

Applicant(s)

WANGH, LAWRENCE J.

Examiner

Deborah Crouch, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 87 and 89-98 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 87 and 89-98 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's arguments filed September 25, 2006 have been fully considered but they are not persuasive. The amendment has been entered. Claims 87 and 89-98 are pending.

The rejection of claims 87 and 89-96 under 35 U.S.C. § 112, first paragraph made in the office action mailed March 23, 2006 is withdrawn in view of Applicant's amendments.

The rejection of claim 97 under 35 U.S.C. 112, second paragraph made in the office action mailed March 23, 2006 is withdrawn in view Applicant's amendment to the claim.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 87-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,480,772 for reasons set forth in the office action mailed March 23, 2006.

Claims 87-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 5,651,992.

Claims 87-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 5,773,217 for reasons set forth in the office action mailed March 23, 2006.

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Claims 87-96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,753,457 for reasons set forth in the office action mailed March 23, 2006.

Claims 87-97 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/969,646 for reasons set forth in the office action mailed March 23, 2006.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant states they have filed terminal disclaimers against the above identified patents or applications. However, no terminal disclaimers have been filed. The rejections are therefore maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 97 stands rejection and new claim 98 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons set forth in the office action mailed March 23, 2006. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 97 and 98 are to a method for cloning a non-human animal from a somatic cell nucleus. However, at the time of filing the art recognized that nuclear transfer or cloning to produce a term animal was unpredictable. Even if applicant's method results in a reprogrammed somatic cell nucleus, it is documented in the arena of nuclear transfer/cloning that pregnancy does not necessarily mean live births.

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Applicant argues the invention disclosed has been successfully demonstrated to reprogram somatic cell nuclei for the production of whole or substantially complete cloned animals. Applicant argues problems with maintaining pregnancy with cloned embryos has not been conclusively shown to be due to inefficient nuclear reprogramming. Applicant states the problems are likely inherent in the reprogramming of higher organisms, and the mechanical manipulation of oocytes and embryos often contribute to the failure to maintain a pregnancy. Applicant argues that Polejaeva et al, Betthausen et al and Campbell et al have produced animals by nuclear transfer. Further, applicant argues the problem with cloning rabbits had to do with the asynchrony between embryo and recipient, and rabbits have been cloned. Applicant argues the invention outlines the conditioning of the donor nuclei in non-activating cytoplasm and activating cytoplasm. These arguments are not persuasive.

The reason for pregnancy failures in the production of cloned animals is not germane to the rejection. The fact remains, at the time of filing obtaining a pregnancy was not a guarantee that a viable cloned animal would be produced. This is the unpredictability. While applicant's reference (The Scientist, 2005) states normal development is an inefficient process, the statements of Pennisi and others directly state normal development of clones is inefficient and unpredictable. Several references summarizing the state of nuclear transfer at the time of filing state reprogramming of somatic cell donor nucleus is root cause of the inefficiency in nuclear transfer (Bourc'his, page 1545, col. 1-2, bridg. parag.; Fairburn, page R68, col. 2, parag. 3; and Hill, page 174, col. 2, parag. 1 and 2). Inefficiency here means unpredictability. These references discuss reprogramming as the core failure of nuclear transfer.

None of Polejaeva et al, Betthausen et al or Campbell et al employee applicant's method of first incubating a somatic cell nucleus in CSF or inactivating egg extract followed by incubation in an activating egg extract. Each of these references introduces the donor

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nucleus into an enucleated oocyte, not an extract, and Polejaeva et al transfers the pronucleus formed by the reconstituted embryo into an enucleated zygote, not an activating egg extract. None of these cited references uses an egg or zygote extract; they use the intact egg or zygote. According to the present specification, a number of eggs are disrupted in a buffer and treated to produce the extract (specification, pages 8-11). Thus, the method of the invention uses a methodology that is not the same as the cited art. The effect of diluting the egg cytoplasm on reprogramming cannot be evaluated. Polejaeva et al, Betthausen et al or Campbell et al each reprogram as part of their cloning methodology, but by a materially different method than that disclosed.

As for rabbits, again the methodology of Chesne does not parallel that disclosed. The rabbits were cloned using intact oocytes, and not an egg extract. Chesne may have been successful using synchronous recipient females and embryos, but this does not address the effect of an egg extract on the successful cloning of rabbits. The disclosed method and that of Chesne, as that of Polejaeva et al, Betthausen et al or Campbell et al, cannot be compared.

Further, it is noted that applicant used inactivating and activating extracts prepared from *Xenopus* eggs. The role of species in reprogramming sufficiently to produce a cloned animal is not clear and cannot be ignored. Given the unpredictable nature of reprogramming and the production of cloned animals, *Xenopus* egg extract may well be able to cause nuclear swelling and chromatin decondensing, but there is no evidence that the extract will reprogram sufficiently to cause the production of a cloned animal. The evidence the ability of *Xenopus* extract to behave as such is seen in the inability of cross-species nuclear transfer (see Meirelles, office action mailed March 23, 2006). Cross-species nuclear transfer resulted in blastocyst formation but no clones.

Therefore the skilled artisan would need to engage in a due amount of experiment without a predictable degree of success to implement the invention as presently claimed.

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The claims are free of the prior art. At the time of filing, the prior art did not teach or suggest methods of nuclear transfer, where the donor nucleus was incubated first in a cytostatic egg extract and second in an activating egg extract.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 7:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Deborah Crouch, Ph.D.
Primary Examiner
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December 1, 2006